

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Continued Curation
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Dr. Rachel Okrent	PERMIT NUMBER:	P526P-18-04180
ORGANIZATION:	Novozymes	APPLICATION NUMBER:	P526-181023-006
ADDRESS:	1445 Drew Ave Davis, CA 95618	FACILITY NUMBER:	N/A
MAILING ADDRESS:	1445 Drew Ave Davis, CA 95618	HAND CARRY:	No
PHONE:	530-757-4775	DATE ISSUED:	11/20/2018
FAX:		EXPIRES:	11/20/2021
DESTINATION:	1445 Drew Ave, Davis, CA 95618		

Under the conditions specified, this permit authorizes the following:				
<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Clavibacter michiganensis subsp nebraskensis	Petri dishes/culture tubes	Research - Growth Chamber (lab included)	Originally Collected from Within the Continental U.S.	
Pantoea stewartii	Petri dishes/culture tubes	Research - Growth Chamber (lab included)	Originally Collected from Within the Continental U.S.	

PERMIT GUIDANCE

This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.

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PPQ HEADQUARTER OFFICIAL VIA EPERMITS.


Osmond Baron

DATE

11/20/2018

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.


PERMIT CONDITIONS

USDA-APHIS issues this permit to Rachel Okrent of Novozymes in Davis, California. This permit authorizes continued curation of the listed regulated materials/organisms received under prior permit (P526P-15-04641) for Research - Growth Chamber (lab included).

1.
 - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:
 - maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
 - not assign or transfer this permit to other persons without APHIS PPQ authorization,
 - maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
 - notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
 - notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of

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regulated materials/organisms,


- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

3. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), *Conothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*), *Ralstonia solanacearum*, *Rathayibacter toxicus*, *Sclerophthora rayssiae*, *Synchytrium endobioticum*, and *Xanthomonas oryzae*.
4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

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5. No new shipments of the regulated articles are authorized under this permit.
6. All research activities, plant inoculations and subsequent disease development must occur at the destination location identified above. This location must have facilities that are adequate to prevent the unauthorized dissemination of the regulated articles received under this permit. Access to this facility must not be accessible to the general public.
7. Vector transmission is not permitted under this authorization. Only mechanical inoculation of plants is permitted.
8. Measures to control potential insect vectors (e.g. black lights, yellow sticky boards, insecticides) must be in place.
9. The regulated materials/organisms listed on this permit are strictly for research in a controlled environment such as a laboratory or growth chamber. This permit is not valid if the regulated materials/organisms will be used for greenhouse research, field research, or release into the environment.
10. Records must be kept of all organisms maintained under this permit. Minimally the record will consist of the name of the organism identified to the lowest taxon possible, the country, or US state/territory, where each isolate was collected, and the date the isolate was received. These records must be made available to Federal and State regulators upon request.
11. Regulated materials/organisms must be stored or maintained in an area that is not accessible to the general public.
12. DEVITALIZATION AND WASTE DISPOSAL


All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility (or see condition #13 below as an alternative). This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste will be double bagged prior to disposal.

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Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.


Any equipment, supplies, tools, secondary shipping containers, packing materials (e.g. ice packs), etc. must be sterilized/sanitized/decontaminated prior to reuse, disposal, or removal from containment.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
 - b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
 - c. The autoclave must be calibrated according to the manufacturer's instructions annually and a written record must be maintained.
 - d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit). You must follow the manufacturer's instructions. If any growth is observed, you must have the autoclave serviced and retested.
13. Devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
 14. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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